

Proposed Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (DL38385)

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Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12202 - MAC B	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12301 - MAC A	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12302 - MAC B	J - L	Maryland

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Novitas Solutions, Inc.	A and B MAC	12401 - MAC A	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12402 - MAC B	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12501 - MAC A	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	District of Columbia Delaware Maryland New Jersey Pennsylvania

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Hypoglossal Nerve Stimulation for the Treatment of
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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for hypoglossal nerve stimulation. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for hypoglossal nerve stimulation and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, Medicare Benefit Policy Manual
 - Chapter 15, Section 60.1 Incident To Physician's Professional Services
 - Chapter 15, Section 110 Durable Medical Equipment - General
- CMS IOM Publication 100-03, Medicare National Coverage Determinations (NCD) Manual,
 - Chapter 1, Part 2, Section 160.7 Electrical Nerve Stimulators
 - Chapter 1, Part 4, Section 240.4 Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA)
 - Chapter 1, Part 4, Section 240.4.1 Sleep Testing for Obstructive Sleep Apnea (OSA)
- CMS IOM Publication 100-04, Medicare Claims Processing Manual, Chapter 20, Section 10.1.1 Durable Medical Equipment (DME)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Obstructive sleep apnea (OSA) is a disease characterized by recurrent episodes of upper airway obstruction during sleep. The disruption in airflow caused by OSA has been associated with multiple comorbidities, including hypertension, cardiovascular disease, cardiac arrhythmia, cerebrovascular disease, excessive daytime sleepiness, and mood disorders. Continuous positive airway pressure (CPAP) has long been the primary treatment modality of choice for OSA, showing improvements in many comorbidities. Unfortunately, despite attempts to improve compliance, many people are unable to tolerate treatment with CPAP. Because of the large percentage of patients not tolerating CPAP, alternative treatment strategies are necessary.

The hypoglossal nerve is the twelfth cranial nerve, and innervates all the extrinsic and intrinsic muscles of the tongue, except for the palatoglossus which is innervated by the vagus nerve. It is a nerve with a solely motor function. The nerve arises from the hypoglossal nucleus in the brain stem as a number of small rootlets, passes through the hypoglossal canal and down through the neck, and eventually passes up again over the tongue muscles it supplies into the tongue. There are two hypoglossal nerves in the body: one on the left, and one on the right.

The concept of stimulating the tongue musculature to increase upper airway size and limit the pathophysiologic obstruction leading to OSA was introduced in the late 1980s. A variety of strategies were utilized, including transcutaneous stimulation with placement of electrodes in the submental region, sublingual mucosa, and soft palate. However, these studies were limited by their lack of selective stimulation of the primary protruder of the tongue, the genioglossus muscle. In 2001, Schwartz et al performed a trial in which they selectively stimulated the branches of the hypoglossal nerve, innervating the genioglossus. They noted a significant improvement in the apnea-hypopnea index (AHI) and O2 desaturation nadir. This technology was subsequently refined, and in 2014 the Stimulation Therapy for Apnea Reduction (STAR) trial was published as the initial clinical trial using upper airway stimulation (UAS) as an alternative therapy to CPAP for treatment of OSA.

The only Food and Drug Administration (FDA) - approved hypoglossal nerve stimulation (HGNS) system has three implantable components: a stimulation lead that delivers mild stimulation to maintain multilevel airway patency during sleep, a breathing sensor lead that senses breathing patterns, and a generator that monitors breathing patterns. The two external components are a patient sleep remote that provides a noninvasive means for a patient to activate the generator and a physician programmer that allows the physician to noninvasively interrogate and configure the generator settings. The system battery life for the implantable components is 7 to 10 years.

A surgeon implants the system containing a neurostimulator subcutaneously in the patient's chest, with one lead attached to the patient's hypoglossal nerve (cranial nerve XII) at the base of the tongue and one lead implanted in the patient's chest. The lead in the chest consists of a pressure sensor that detects breathing. Information about respiration rate is relayed to the device, which stimulates the hypoglossal nerve in the tongue. When stimulated, the tongue moves forward, opening the airway. The patient can operate the device by remote control, which the patient activates before going to sleep. The device turns on after 20 minutes to minimize disrupting the patient's sleep onset; the device must be manually turned off via remote when the patient wakes.

Covered Indications

FDA-approved hypoglossal nerve neurostimulation is considered medically reasonable and necessary for the

treatment of moderate to severe obstructive sleep apnea when **all** of the following criteria are met:

1. Beneficiary is 22 years of age or older; **and**
2. Body mass index (BMI) is less than 35 kg/m²; **and**
3. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; and
4. Beneficiary has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **and**
5. AHI is 15 to 65 events per hour; **and**
6. Beneficiary has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert: **and**
7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; **and**
8. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

Limitations

The following are considered not reasonable and necessary and therefore will be denied:

1. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for all other indications.
2. Non-FDA-approved hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for the treatment of adult obstructive sleep apnea due to insufficient evidence of being safe and effective.
3. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary when any of the following contraindications are present:
 - Beneficiaries with central and mixed apneas that make up more than one-quarter of the total AHI.
 - Beneficiaries with an implantable device could experience unintended interaction with the HGNS implant system. Limitations are:
 - BMI equal to or greater than 35
 - Neuromuscular disease
 - Hypoglossal-nerve palsy
 - Severe restrictive or obstructive pulmonary disease
 - Moderate-to-severe pulmonary arterial hypertension
 - Severe valvular heart disease
 - New York Heart Association class III or IV heart failure
 - Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months)
 - Persistent uncontrolled hypertension despite medication use
 - Active psychiatric disease
 - Coexisting nonrespiratory sleep disorders that would confound functional sleep assessment
 - Beneficiaries who are, or who plan to become pregnant.
 - Beneficiaries who require Magnetic Resonance Imaging (MRI) with model 3024.
 - Beneficiaries, who require MRI with model 3028, can undergo MRI on the head and extremities if certain conditions and precautions are met. Please refer to the Manufacturer Guidelines for this model and future models for more information.
 - Beneficiaries who are unable or do not have the necessary assistance to operate the sleep remote.
 - Beneficiaries with any condition or procedure that has compromised neurological control of the upper airway.
4. Drug Induced Sleep Endoscopy (DISE):
 - Due to documented inconsistency in determining if complete concentric collapse (CCC) is present, the

inserting provider shall be certified by the FDA approved manufacturer's second opinion service of validation via video clip submissions of at least 80% agreement in at least 15 consecutive studies.

Inserting providers shall have documentation to submit to this contractor if necessary.

5. Shared Decision Making (SDM):

- SDM shall be documented in the patient's record by the referring physician and the implanting physician. Both shall provide these documents if requested by this contractor.

Place of Service (POS)

Hypoglossal nerve stimulation for the treatment of OSA must be furnished in accordance with the accepted standards of medical practice in a setting appropriate to the patient's medical needs and condition.

Provider Qualifications

Hypoglossal nerve stimulation for the treatment of OSA must be ordered and furnished by qualified personnel. The hypoglossal nerve (HN) may be damaged during neck surgeries. A detailed understanding of the anatomy of the hypoglossal nerve in relation to various anatomical landmarks and surrounding structures is important to reduce procedural complications and the risk of nerve damage.

- **Provider Specialties**

- Insertion of hypoglossal nerve stimulation addressed in this LCD must be performed by a qualified physician (MD or DO) who is a board certified **otolaryngologist** having completed a residency and/or fellowship program and maintains ongoing certification in otolaryngology.
- Insertion of an FDA-approved hypoglossal nerve stimulation device must be performed by a qualified physician who completed the appropriate AMA or AOA certified residency program in otolaryngology. In addition, prior to implanting the system, surgeons will need to receive classroom instruction by an FDA approved device manufacturer or equivalent on device implant techniques as well as cadaver training. Documentation must be provided to support completion of training to an exemplary level by the manufacture. Sleep physicians and sleep technicians shall receive classroom instruction from a similar facility on how to titrate the device including hands on operation of the programmer. Doctors must maintain, for the contractor to review, documentation of such training completion to a satisfactory level of completion as established by the device manufacturer or appropriate board approval of competency. Evaluation, referral and post implant evaluation of the hypoglossal nerve stimulator, but not including expected post-op care by the inserting physician, should be performed by board eligible or certified sleep physician with qualifications as outlined in LCD L35050, Outpatient Sleep Studies. Sleep Technicians shall meet the same qualifications as outlined in the LCD L35050, Outpatient Sleep Studies, in addition. Likewise, sleep studies shall be performed in an accredited sleep facility as stated in LCD L35050.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

Summary of Evidence

Published Literature

STAR Trial 12 month follow-up:

Strollo, et al. for the STAR Trial Group evaluated the clinical safety and effectiveness of upper-airway stimulation at 12 months for the treatment of moderate-to-severe obstructive sleep apnea¹. The study included 126 participants; 83% were men. The mean age was 54.5 years, and the mean BMI was 28.4. Exclusion criteria were a BMI of more than 32.0, neuromuscular disease, hypoglossal-nerve palsy, severe restrictive or obstructive pulmonary disease, moderate-to-severe pulmonary arterial hypertension, severe valvular heart disease, New York Heart Association class III or IV heart failure, recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months), persistent uncontrolled hypertension despite medication use, active psychiatric disease, and coexisting nonrespiratory sleep disorders that would confound functional sleep assessment. The study was designed by the sponsor (Inspire Medical Systems), the investigators, and the FDA as a multicenter, prospective, single-group trial with participants serving as their own controls. The primary outcome evaluation was followed by a randomized, controlled therapy-withdrawal study that included a subgroup of consecutive participants selected from the population that had a response to therapy. The primary outcome measures were assessed by means of overnight polysomnography and scored by an independent core laboratory with the use of standard criteria. The data analysis was performed by the independent statistician.

Participants underwent screening that included polysomnography, medical and surgical consultation, and endoscopy during drug-induced sleep. Participants were excluded if the AHI score from the screening polysomnography was less than 20 or more than 50 events per hour, if central or mixed sleep-disordered breathing events accounted for more than 25% of all apnea and hypopnea episodes, or if the AHI score while the person was not in a supine position was less than 10 events per hour. Participants were also excluded if pronounced anatomical abnormalities preventing the effective use or assessment of upper-airway stimulation were identified during the surgical consultation (e.g., tonsil size of 3 or 4 [tonsils visible beyond the pillars or extending to midline]) or if complete concentric collapse at the retropalatal airway was observed on endoscopy performed during drug-induced sleep. Qualified participants underwent a surgical procedure to implant the upper-airway stimulation system (Inspire Medical Systems). The stimulation electrode was placed on the hypoglossal nerve to recruit tongue-protrusion function; the sensing lead was placed between the internal and external intercostal muscles to detect ventilatory effort; the neurostimulator was implanted in the right ipsilateral mid-infraclavicular region.

The primary outcome was the change in the severity of obstructive sleep apnea in the study population, as assessed by means of the AHI and the oxygen desaturation index (ODI; the number of times per hour of sleep that the blood oxygen level drops by greater than or equal to 4 percentage points from baseline). The co-primary outcome was the proportion of participants with a response from baseline to 12 months with respect to the primary outcome measures of the AHI and ODI scores. A response as measured by means of the AHI was defined as a reduction of at least 50% from baseline in the AHI score and an AHI score on the 12-month polysomnography of less than 20 events per hour. The ODI was chosen as a stable integrative outcome value of all forms of sleep-disordered breathing. A response as measured by means of the ODI was defined as a reduction of at least 25% from baseline in the ODI score. The prespecified primary efficacy objectives were response rates of at least 50%, as assessed by means of the AHI and ODI. All participants who received an implant were included in the primary outcome analysis; participants who did not complete the 12-month visit were considered not to have had a response.

Secondary outcome measures included self-reported sleepiness and disease-specific quality of life as assessed with the use of the Epworth Sleepiness Scale (scores range from 0.0 to 24.0, with higher scores indicating more daytime sleepiness), disease-specific quality of life, as assessed with the use of the Functional Outcomes of Sleep Questionnaire (FOSQ; scores range from 5.0 to 20.0, with higher scores indicating greater functioning), and the percentage of sleep time with the oxygen saturation less than 90%.

At the 12-month visit, the first 46 consecutive participants who met the criterion of having a response to therapy were randomly assigned, in a 1:1 ratio, to the therapy-maintenance group or the therapy-withdrawal group¹. This design filtered out persons who had not had a response to therapy. The therapy-withdrawal group had the device turned off for 7 days, whereas the therapy-maintenance group continued with the device turned on. Polysomnography was performed after the randomization period to measure the effects of therapy withdrawal, as

compared with continued use of the therapy.

The scores on the AHI and ODI (primary outcome measures) were lower (indicating fewer episodes of sleep apnea) at 12 months than at baseline. The median AHI score decreased 68%, from the baseline value of 29.3 events per hour to 9.0 events per hour. The median ODI score decreased 70%, from 25.4 events per hour to 7.4 events per hour. At the 12-month visit, the criteria for the coprimary outcome of a reduction of at least 50% in the AHI score from baseline and an AHI score of less than 20 events per hour were met by 66% of the participants (83 of 126 participants; lower boundary of the 97.5% confidence interval [CI], 57). The criterion for the coprimary outcome of a reduction of at least 25% in the ODI score from baseline was met by 75% of participants (94 of 126; lower boundary of the 97.5% CI, 66). Both primary efficacy outcomes exceeded the predefined study objectives.

Scores on the FOSQ and Epworth Sleepiness Scale indicated significant improvement at 12 months, as compared with baseline. The median percentage of sleep time with the oxygen saturation less than 90% decreased from a baseline value of 5.4% to 0.9% at 12 months. The average increase in the AHI score in the therapy-withdrawal group was 18.2 events per hour, whereas the average increase in the therapy-maintenance group was 1.7 events per hour (difference in changes in mean scores, 16.4 ± 12.0 events per hour; P less than 0.001). A similar effect was observed with respect to the mean ODI scores.

Two participants had a serious device-related adverse event requiring repositioning and fixation of the neurostimulator to resolve discomfort. No permanent tongue weakness was reported during the study. Most of the device-related events that were not considered to be serious resolved after the participants acclimated to the upper-airway stimulation therapy or after the device was reprogrammed to adjust the stimulation variables.

The daily use of upper-airway stimulation was 86%, as assessed on the basis of self-report. A control group of therapeutic CPAP users (i.e., a comparative-effectiveness design) would be impractical, given the current study design.

The randomized, controlled therapy-withdrawal study in which some participants had the therapy turned off for 1 week provided evidence that the therapeutic effect established at 12 months was attributable to the upper-airway stimulation therapy, rather than variability in the AHI score.

STAR Trial 18 month follow-up:

Dedhia, et al. for the STAR Trial Group evaluated the stability of improvement in polysomnographic measures of sleep disordered breathing, patient reported outcomes, the durability of hypoglossal nerve recruitment and safety at 18 months in the Stimulation Treatment for Apnea Reduction (STAR) trial participants². This was a prospective multicenter single group trial with participants serving as their own controls. Primary outcome measures were the apnea-hypopnea index (AHI) and the 4% oxygen desaturation index (ODI). Secondary outcome measures were the Epworth Sleepiness Scale (ESS), the Functional Outcomes of Sleep Questionnaire (FOSQ), and oxygen saturation percent time less than 90% during sleep. Stimulation level for each participant was collected at three predefined thresholds during awake testing. Procedure- and/or device-related adverse events were reviewed and coded by the Clinical Events Committee.

The median AHI was reduced by 67.4% from the baseline of 29.3 to 9.7/h at 18 months. The median ODI was reduced by 67.5% from 25.4 to 8.6/h at 18 months. The FOSQ and ESS improved significantly at 18 months compared to baseline values. The functional threshold was unchanged from baseline at 18 months. Two participants experienced a serious device-related adverse event requiring neurostimulator repositioning and fixation. No tongue weakness reported at 18 months.

The authors concluded that upper airway stimulation via the hypoglossal nerve maintained a durable effect of improving airway stability during sleep and improved patient reported outcomes (Epworth Sleepiness Scale and

Functional Outcomes of Sleep Questionnaire) without an increase of the stimulation thresholds or tongue injury at 18 months of follow-up.

STAR Trial 24 month follow-up:

On behalf of the STAR Trial, investigators evaluated the long-term (24-month) effect of cranial nerve upper airway stimulation (UAS) therapy on patient-centered obstructive sleep apnea (OSA) outcome measures³. This was a prospective, multicenter, cohort study of 126 patients with moderate to severe OSA who had difficulty adhering to positive pressure therapy and received the surgically implanted UAS system. Outcomes were measured at baseline and postoperatively at 12 months and 24 months, and included self- and bedpartner-report of snoring intensity, Epworth Sleepiness Scale (ESS), and Functional Outcomes of Sleep Questionnaire (FOSQ). Additional analysis included FOSQ subscales, FOSQ-10, and treatment effect size.

Significant improvement in mean FOSQ score was observed from baseline (14.3) to 12 month (17.3), and the effect was maintained at 24 month (17.2). Similar improvements and maintenance of effect were seen with all FOSQ subscales and FOSQ-10. Subjective daytime sleepiness, as measured by mean ESS, improved significantly from baseline (11.6) to 12 month (7.0) and 24 month (7.1). Self-reported snoring severity showed increased percentage of "no" or "soft" snoring from 22% at baseline to 88% at 12 months and 91% at 24 months. UAS demonstrated large effect size (greater than 0.8) at 12 and 24 months for overall ESS and FOSQ measures, and the effect size compared favorably to previously published effect size with other sleep apnea treatments.

The authors concluded that in a selected group of patients with moderate to severe OSA and body mass index less than or equal to 32 kg/m², hypoglossal cranial nerve stimulation therapy can provide significant improvement in important sleep related quality-of-life outcome measures and the effect is maintained across a 2-year follow-up period.

STAR Trial 36 month follow-up:

On behalf of the STAR Trial, investigators describe the 36-month clinical and polysomnography (PSG) outcomes in an obstructive sleep apnea (OSA) cohort treated with hypoglossal cranial nerve upper airway stimulation (UAS)⁴.

Of 126 enrolled participants, 116 (92%) completed 36-month follow-up evaluation per protocol; 98 participants additionally agreed to a voluntary 36-month PSG. Self-report daily device usage was 81%. In the PSG group, 74% met the a priori definition of success with the primary outcomes of apnea-hypopnea index, reduced from the median value of 28.2 events per hour at baseline to 8.7 and 6.2 at 12 and 36 months, respectively. Similarly, self-reported outcomes improved from baseline to 12 months and were maintained at 36 months. Soft or no snoring reported by bed partner increased from 17% at baseline to 80% at 36 months. Serious device-related adverse events were rare, with 1 elective device explantation from 12 to 36 months.

The authors concluded that long-term 3-year improvements in objective respiratory and subjective quality-of-life outcome measures are maintained. Adverse events are uncommon. UAS is a successful and appropriate long-term treatment for individuals with moderate to severe OSA.

STAR Trial 48 month follow-up:

On behalf of the STAR Trial, investigators assess patient-based outcomes of participants in a large multicenter prospective cohort study-the STAR trial-48 months after implantation with an upper airway stimulation system for moderate to severe obstructive sleep apnea⁵.

A total of 91 subjects completed the 48-month visit. Daytime sleepiness as measured by ESS was significantly reduced (P equal to .01), and sleep-related quality of life as measured by FOSQ significantly improved (P equal to .01) when compared with baseline. Soft to no snoring was reported by 85% of bed partners. Two patients required additional surgery without complication for lead malfunction.

The authors concluded that upper airway stimulation maintained a sustained benefit on patient-reported outcomes (ESS, FOSQ, snoring) at 48 months in select patients with moderate to severe obstructive sleep apnea.

STAR Trial 5 year outcomes:

On behalf of the STAR Trial, investigators present 5-year outcomes from a multicenter prospective cohort of patients with obstructive sleep apnea (OSA) who were treated with upper airway stimulation (UAS) via a unilateral hypoglossal nerve implant⁶. From a cohort of 126 patients, 97 completed protocol, and 71 consented to a voluntary polysomnogram. Those having continuous positive airway pressure failure with moderate to severe OSA, body mass index less than 32 kg/m², and no unfavorable collapse on drug-induced sleep endoscopy were enrolled in a phase 3 trial. Prospective outcomes included apnea-hypopnea index (AHI), oxygen desaturation index, and adverse events, as well as measures of sleepiness, quality of life, and snoring.

Patients who did and did not complete the protocol differed in baseline AHI, oxygen desaturation index, and Functional Outcomes of Sleep Questionnaire scores but not in any other demographics or treatment response measures. Improvement in sleepiness (Epworth Sleepiness Scale) and quality of life was observed, with normalization of scores increasing from 33% to 78% and 15% to 67%, respectively. AHI response rate (AHI less than 20 events per hour and greater than 50% reduction) was 75% (n equal to 71). When a last observation carried forward analysis was applied, the responder rate was 63% at 5 years. Serious device-related events all related to lead/device adjustments were reported in 6% of patients.

The authors concluded that there were improvements in sleepiness, quality of life, and respiratory outcomes are observed with 5 years of UAS. Serious adverse events are uncommon. UAS is a nonanatomic surgical treatment with long-term benefit for individuals with moderate to severe OSA who have failed nasal continuous positive airway pressure.

Evidence-Based Practice Guidelines and Position Statements

American Academy of Sleep Medicine

The American Academy of Sleep Medicine (AASM) Clinical Practice Guideline for Diagnostic Testing for Adult OSA states that the third edition of the International Classification of Sleep Disorders (ICSD-3) defines OSA as a PSG-determined obstructive respiratory disturbance index (RDI) greater than or equal to 5 events/hour associated with the typical symptoms of OSA (e.g., unrefreshing sleep, daytime sleepiness, fatigue or insomnia, awakening with a gasping or choking sensation, loud snoring, or witnessed apneas), or an obstructive RDI greater than or equal to 15 events/hour (even in the absence of symptoms).

American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS)

In 2016, the American Academy of Otolaryngology Head and Neck Surgery issued a position statement on hypoglossal nerve stimulation for treatment of obstructive sleep apnea (OSA) which states "The American Academy of Otolaryngology Head and Neck Surgery considers upper airway stimulation (UAS) via the hypoglossal nerve for the treatment of adult obstructive sleep apnea syndrome to be an effective second-line treatment of moderate to severe obstructive sleep apnea in patients who are intolerant or unable to achieve benefit with positive pressure therapy (PAP). Not all adult patients are candidates for UAS therapy and appropriate polysomnographic, age, BMI and objective upper airway evaluation measures are required for proper patient selection."

International Society for Sleep Surgery

International Society for Sleep Surgery states that Cranial nerve (hypoglossal nerve) stimulation is among surgical treatments and procedures that "have been shown to be effective in the treatment of sleep disordered breathing/obstructive sleep apnea syndrome in adults (and/or children) when applied to selected patients based on their anatomy, physiology, body mass index and neck size, prior therapy and co-morbidities. Patient should have undergone an appropriate evaluation(s) prior to treatment which may include polysomnography, home sleep testing,

awake or drug induced sleep endoscopy, and possible cephalometric or other radiographic evaluations.”

National Institute for Health and Clinical Excellence (NICE)

In 2017, National Institute for Health and Clinical Excellence (NICE) issued an interventional procedure guidance (IPG598) which states: “Current evidence on the safety and efficacy of hypoglossal nerve stimulation for moderate to severe obstructive sleep apnea is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit for research.”

**Analysis of Evidence
(Rationale for Determination)**

The evidence on hypoglossal nerve stimulation for the treatment of obstructive sleep apnea (OSA) includes case series and a multicenter, prospective, single group, cohort design study (STAR) that were surgically implanted with an upper airway stimulation device with obstructive sleep apnea who had difficulty either accepting or adhering to CPAP therapy and were followed for 5 years. Prospective cohort study is gold standard for epidemiologic studies. The study strengths included measuring primary and secondary outcomes and at 12-month visits, a second randomized study within the study where participants were randomly assigned into two groups with one group having the device turned off for 7 days and the other continued with the device turned on. Polysomnography was performed after the randomization period to measure the effects of therapy withdrawal as compared to continued use of the therapy¹.

Hypoglossal nerve stimulation has shown improved outcomes in this single arm study when used in a select group of patients. For the patients that met the inclusion criteria for AHI, BMI and favorable pattern for palatal collapse about two-thirds met the study definition of success. Results observed at the 12 month follow-up were maintained at 3 years. Patient based outcomes at 48 months, concluded these patients maintained a sustained benefit on patient reported outcomes (Epworth Sleepiness Score, Functional Outcomes of Sleep Questionnaire and snoring). Conclusions from the 5 year outcomes were that UAS is a nonanatomic surgical treatment with long-term benefit for individuals with moderate to severe OSA who have failed nasal continuous positive airway pressure. Safety and effectiveness were evaluated using multiple outcome measures.

For Individuals with obstructive sleep apnea who are treated with hypoglossal nerve stimulation, the evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome when utilized as outlined in this LCD.

Coding Information

Refer to A56938, Future Effective Local Coverage Article, Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea.

Proposed Process Information

Synopsis of Changes

CHANGES	FIELDS CHANGED
Not Applicable	N/A

Associated Information

Utilization Guidelines

Please refer to the Local Coverage Article: Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (A56938) for utilization guidelines that apply to the reasonable and necessary provisions outlined in this LCD.

Sources of Information

Contractor is not responsible for the continued viability of websites listed.

Other Policies

Aetna Medical Clinical Policy Bulletin Number: 0004. Obstructive Sleep Apnea in Adults. Last Review 07/06/2018.

Florida Blue Medical Coverage Guideline (MCG) 02-40000-16. Medical & Surgical Management of Obstructive Sleep Apnea (OSA), Snoring, and Other Conditions of the Soft Palate and Nasal Passages. Reviewed 10/31/2017.

Wellmark Medical Policy 07.01.68. Implantable Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea. Reviewed April 2018.

Contractor Medical Directors

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Open Meetings

MEETING DATE	MEETING STATE(S)	MEETING INFORMATION
09/13/2019	Arkansas Colorado Delaware District of Columbia Louisiana Maryland Mississippi New Jersey New Mexico Oklahoma Pennsylvania Texas	The open meeting is a meeting for JH and JL. The meeting will be held at Mechanicsburg office of Novitas Solutions, Inc. at 2020 Technology Parkway, Mechanicsburg, PA 17050.

Contractor Advisory Committee (CAC) Meetings

MEETING DATE	MEETING STATE(S)	MEETING INFORMATION
06/13/2019	Arkansas Colorado Delaware District of Columbia Louisiana Maryland Mississippi New Jersey New Mexico Oklahoma Pennsylvania Texas	The CAC meeting is a joint meeting for JN JH and JL. The meeting was held at Mechanicsburg office of Novitas Solutions, Inc. at 2020 Technology Parkway, Mechanicsburg, PA 17050.

MAC Meeting Information URL(s)

N/A

Proposed LCD Posting Date

08/29/2019

Comment Period Start Date

08/29/2019

Comment Period End Date

10/13/2019

Released to Final LCD Date

Please Note: This is not the LCD Effective Date.

N/A

Reason for Proposed LCD

- Other (Provider Inquiry)

Proposed Contact

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

CODE	DESCRIPTION
999x	Not Applicable

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

CODE	DESCRIPTION
99999	Not Applicable

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
XX000	Not Applicable

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
XX000	Not Applicable

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
XX000	Not Applicable

Additional ICD-10 Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A56938 - Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea

LCD(s)

L35448 - Independent Diagnostic Testing Facility (IDTF)

Related National Coverage Documents

NCD(s)

160.7 - Electrical Nerve Stimulators

240.4 - Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA)

240.4.1 - Sleep Testing for Obstructive Sleep Apnea (OSA)

Keywords

N/A